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RD2009-06

Registration Decision

Pantoea agglomerans **Strain E325**

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Overview

Registration Decision for *Pantoea agglomerans* strain E325

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Bloomtime Biological Technical and Bloomtime Biological FD Biopesticide, containing the microbial pest control agent *Pantoea agglomerans* strain E325, to suppress fire blight (*Erwinia amylovora*) on apple and pear trees, Saskatoon berries, caneberries and non-bearing pome fruit nursery stock.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document¹ Proposed Registration Decision PRD2009-01, *Pantoea agglomerans* strain E325. This Registration Decision² describes this stage of the PMRA's regulatory process for *Pantoea agglomerans* strain E325 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-01. This decision is consistent with the proposed registration decision stated in PRD2009-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-01, *Pantoea agglomerans* strain E325, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

What is *Pantoea agglomerans* strain E325?

Pantoea agglomerans is a bacterium that is ubiquitous in nature and occurs naturally on fruit trees. As the active ingredient in Bloomtime Biological FD Biopesticide, it colonizes the flowers of fruit trees and occupies sites that would otherwise be colonized by the fireblight pathogen, *Erwinia amylovora*. The growth of *Pantoea agglomerans* strain E325 on fruit blossoms suppresses the ability of *Erwinia amylovora* to grow and reach levels necessary to trigger fireblight disease development.

Health Considerations

Can Approved Uses of *Pantoea agglomerans* Strain E325 Affect Human Health?

***Pantoea agglomerans* strain E325 is unlikely to affect your health when Bloomtime Biological FD Biopesticide is used according to label directions.**

Exposure to *Pantoea agglomerans* strain E325 may occur during handling and application of the product. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g. production of toxic byproducts); reports of any adverse incidents; its potential for pathogenicity, infectivity and toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses to identify any potential pathogenicity, infectivity and toxicity concerns. No significant toxicity and no signs of pathogenicity or infectivity were observed when *Pantoea agglomerans* strain E325 was tested on laboratory animals.

Other strains of *Pantoea agglomerans* found in nature have been associated with minor wound infections involving punctured skin, but there is no indication that it can cause localized infections by penetrating the intact skin of healthy individuals. This species of microorganism is not a primary human pathogen and is not known to produce byproducts that are harmful to humans or other animals.

Pantoea agglomerans strains produce a substance on their cell walls called lipopolysaccharide which can be shed from the cells as microscopic vesicles. If inhaled in large amounts, the lipopolysaccharide of *Pantoea agglomerans* can cause a respiratory inflammatory reaction. A condition known as respiratory hypersensitivity could therefore develop in people such as farm workers and applicators upon repeated exposure to this product. Like all bacteria, *Pantoea agglomerans* strain E325 contains other substances that can cause allergic reactions in people who are exposed repeatedly to it at high concentrations. However, these reactions can be avoided if farm workers and applicators follow label recommendations to minimize or limit exposure to Bloomtime Biological FD Biopesticide.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Pantoea agglomerans strains are common in nature and applying Bloomtime Biological FD Biopesticide to apple and pear trees is not expected to significantly increase the natural environmental background levels of this microorganism. Few bacteria are expected to remain as residues on the fruit at harvest because the product is applied to fruit trees at bloom time, well before fruit are present. No adverse effects have been attributed to dietary exposure from natural populations of *Pantoea agglomerans*. Also, no significant toxicity and no signs of pathogenicity were observed when *Pantoea agglomerans* strain E325 was administered orally to rats, and there are no reports of known mammalian toxins being produced by the bacterium. The establishment of a maximum residue limit (MRL) is therefore not required for *Pantoea agglomerans* strain E325.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit. Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. Furthermore, the likelihood of residues of *Pantoea agglomerans* strain E325 contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks from Handling Bloomtime Biological FD Biopesticide

Occupational risks are not of concern when Bloomtime Biological FD Biopesticide is used according to label directions, which include protective measures.

Pesticide applicators handling or applying Bloomtime Biological FD Biopesticide and field workers re-entering orchards where trees were sprayed can come into direct contact with *Pantoea agglomerans* strain E325 on the skin, in the eyes, or by inhalation. For this

reason, the label will specify that farm workers exposed to Bloomtime Biological FD Biopesticide must wear waterproof gloves, long-sleeved shirts, long pants, shoes, socks and a dust/mist filtering mask. Furthermore, early entry workers will be restricted from entering orchards treated with Bloomtime Biological FD Biopesticide for up to 4 hours after spraying unless they are wearing the appropriate personal protective equipment.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Bloomtime Biological FD Biopesticide is Introduced Into the Environment?

Environmental risks are not of concern.

There are no published reports of disease associated with *Pantoea agglomerans* in wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, algae and aquatic plants. Therefore, Bloomtime Biological FD Biopesticide is expected to present a negligible risk to these non-target organisms. Only rare cases of disease caused by wild strains of *Pantoea agglomerans* have been reported in plants, including cotton, onion, garlic, beach pea and seedlings of such conifer (evergreen) species as Douglas fir. *Pantoea agglomerans* does not affect apple or other pome fruit trees. Given the narrow range of plant species that have been infected by wild strains of this bacterium and the limited use pattern of *Pantoea agglomerans* strain E325 in apple and pear orchards, the likelihood of non-target plants of commercial or environmental importance being impacted by Bloomtime Biological FD Biopesticide is minimal. However, as a precautionary measure to protect commercially important stands of conifer trees, the product label will instruct users to avoid spraying orchards adjacent to newly planted conifer forestry blocks.

Value Considerations

What Is the Value of Bloomtime Biological FD Biopesticide?

Bloomtime Biological FD Biopesticide is registered to suppress fireblight on apples, pears, Saskatoon berries, caneberries and non-bearing pome fruit nursery stock.

Bloomtime Biological FD Biopesticide is an alternative product to Streptomycin 17, a bactericide currently registered for fireblight control that has important resistance management issues. Bloomtime Biological FD Biopesticide is compatible with streptomycin and should be used in an integrated fireblight suppression program. Suppression of the fireblight pathogen (*Erwinia amylovora*) with Bloomtime Biological FD Biopesticide will reduce grower reliance on streptomycin.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Bloomtime Biological FD Biopesticide to address the potential risks identified in this assessment are as follows.

Human Health

Due to a concern with users developing allergic reactions through repeated high exposures to *Pantoea agglomerans* strain E325, anyone handling or applying Bloomtime Biological FD Biopesticide must wear waterproof gloves, a long-sleeved shirt, long pants, shoes, socks and a dust/mist filtering mask. Furthermore, early-entry workers will be restricted from entering orchards treated with Bloomtime Biological FD Biopesticide for up to four hours after spraying unless the appropriate personal protective equipment is worn.

Environment

As wild strains of *Pantoea agglomerans* have been known to cause gall disease in some conifer tree species, including the commercially important Douglas fir, the Bloomtime Biological FD Biopesticide label will direct users to avoid applying the product to apple or pear orchards that are adjacent to newly planted conifer forestry blocks.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/revision-final/index-eng.php) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

Chemistry

PMRA Document Number 1525866

Reference DACO: 0.8

PMRA Document Number 1525877 2007.

Reference Bloomtime Biological FD Biopesticide, Product Characterization and Analysis: Manufacturing Method and Quality Assurance. Project ID 07-PRA-NAP-002. November 30, 2007. DACO: M2.8

PMRA Document Number 1525881

Reference DACO: 0.0

PMRA Document Number 1605528

Reference 2008. PMRA Clarification Response. June 6, 2008.

PMRA Document Number 1525539 2007.

Reference Correspondence- Applicant. December 10, 2007. DACO: 0.8

PMRA Document Number 1525552

Reference United States Department of Agriculture- Agriculture Research Service-Tree Fruit Research Laboratory. 2007. Bloomtime Biological Technical Biopesticide, Product Characterization and Analysis: Origin, Derivation, and Identification of the MPCA(s). Project ID 07-PRA-NAP-001. November 30, 2007. DACO: M2.7.1

PMRA Document Number 1525557

Reference DACO: 0.0 Index

2.0 Value

PMRA Document Number 1461141

Reference 2007-5793, PMUC cover letter and rationale, DACO: 0.8

PMRA Document Number 1461142

Reference 2007-5793, Registrant letter of support and rationale, DACO: 0.8.3

